

REMARKS

Claims 1-14 and 20-22 are presently pending in the application.

At the outset, applicants note that attempts were made to schedule an interview with the Examiner in early December, but were unsuccessful due to a snow storm and the schedules of the Examiner and the undersigned. In the event that the present Amendment and Remarks do not place the application in condition for allowance, applicants request an interview with the Examiner to further discuss this case to determine what may be needed to place the application in condition for allowance, in view of the long prosecution of this application and its parent applications.

Claim 1 has been amended to positively recite as a method step "allowing the salicylic acid to be present as a solution on the surface of the skin for a time sufficient to produce a chemical peel of stratum corneum of the skin with viable epidermis remaining substantially intact." In contrast, the prior version of claim 1 could have been interpreted to merely allow for the possibility of the topical application to result in a chemical skin peel. Neither Blank nor Damani, et al., relied on by the Examiner, teach or suggest allowing the salicylic acid to be present as a solution on a surface of the skin for a time sufficient to produce a chemical peel of the stratum corneum of the skin with viable epidermis remaining substantially intact.

Thus, as previously pointed out at pages 3-5 of the Request for Reconsideration filed November 2, 2001, both Blank and Damani teach persistent or chronic application of their compositions containing salicylic acid. A solution containing at least 15 wt % salicylic acid as applied according to the present invention cannot be used as a persistent or chronic treatment because of the irritation and chemical peeling which it causes. Therefore, as previously pointed out, both Blank and Damani, et al., teach away from the superficial chemical skin peel of the present invention.

In response to applicants previous arguments, the Examiner first states (middle of page 4 of Office Action) that the recitation of a newly-discovered function or property, inherently possessed by things in the prior art, does not cause claims drawn to those things to distinguish over the prior art. However, the Examiner is mistaken in her assumption that the prior art inherently possesses the function or property of the present invention. In order to rely on inherency as a basis for rejection, the Examiner must establish that the prior art necessarily practices the present invention and achieves the function or property obtained by applicant. It is

not sufficient that there be a mere possibility within the scope of the prior art of practicing the claimed invention and achieving the function or property obtained by the applicant. Clearly, the Examiner has not made such a showing of necessity, and hence inherency, in the present case.

The Examiner seems to contend that merely because Blank states a broad range of 0.01% to 50% of salicylic acid in his topical pharmaceutical compositions, this inherently teaches the present invention. However, as pointed out at the bottom of page 3 of the Request for Reconsideration filed November 2, 2001, this range of Blank is at best prophetic, since salicylic acid is not even soluble in ethanol or similar volatile liquid solvents at concentrations much above 30%. Moreover, high concentrations of salicylic acid would not be safe and effective amounts for the chronic treatment taught by Blank. Further, the specific examples of Blank contain no more than 2 wt % salicylic acid, and even these use water and various emollients and other ingredients to allow for safe and effective chronic treatment. Therefore, taking the teachings of Blank as a whole, there is nothing which would necessarily result in one skilled in the art using a 15 wt % or more salicylic acid solution in a volatile, liquid solvent and allowing the solution to remain on the surface of the skin for a time sufficient to produce a chemical peel. Accordingly, the Examiner has not established that the present invention would be inherently possessed in the prior art.

The same must be said for Damani, et al., who also do not necessarily practice the present invention and achieve the function or property obtained by applicant. The Examiner notes that Damani, et al., teach between about 1% and 25% by weight of salicylic acid in their formula. However, as in Blank, the compositions of Damani, et al., are intended for persistent or chronic application, preferably one or more times daily (see col. 4, lines 50-52). Moreover, as pointed out at the bottom of page 3 of the Request for Reconsideration filed November 2, 2001, the benzoyl peroxide and salicylic acid are not present as a solution in a volatile, liquid solvent, but rather are dispersed in an aqueous gel. Further, the specific examples of Damani, et al., use only 4% and 7.5% salicylic acid, nowhere near the at least 15% salicylic acid used in the solutions of the present invention.

Finally, in response to applicants distinction between the one application peel of the present invention and the chronic or persistent application of Blank and Damani, et al., the Examiner asserts (bottom of page 5 of the Office Action) that a recitation of intended use of the claimed invention must result in structural differences between the claimed invention and the

prior art. The Examiner further asserts that if the prior art structure is capable of performing the intended use, then it meets the claim. Again, the Examiner's application of the law to this case is inappropriate.

First, there is clearly a structural difference between the claimed invention and the prior art. Whereas the present invention specifically allows the high concentration salicylic acid solution to be present on a surface of the skin for a time sufficient to produce a chemical peel, both Blank and Damani, et al., teach away from the production of a peel. Blank specifically seeks to avoid irritation and peeling, and both Blank and Damani, et al., seek to use their compositions for persistent or chronic application, which are inconsistent with a solution and application which intentionally produces peeling.

Second, the Examiner is mistaken when she asserts that the prior art structure is capable of performing the intended use. Thus, when taking the teachings of each of the prior art references as a whole, which one must do in considering the prior art, it is not possible to use the teachings of Blank and Damani, et al., to perform the intended use of the present invention, because Blank and Damani, et al., teach methods of application which are inconsistent with chemical peeling. The Examiner cannot ignore the teachings of the references in attempting to make them capable of performing the intended use of the present invention.

Third, to the extent that the Examiner is relying on inherency, as noted above, it is not sufficient that the prior art structure be merely capable of performing the intended use, it must necessarily perform the intended use. That is, merely because Blank and Damani, et al., teach a broad range of concentrations of salicylic acid which overlaps the range of the present invention, does not mean that one skilled in the art could or would select a concentration of salicylic acid in the upper portions of those ranges. Instead, one skilled in the art would look to the teachings of Blank and Damani, et al., which require compositions suitable for persistent or chronic application. Given those requirements, one skilled in the art would have rejected concentrations in the high ends of the Blank and Damani, et al., ranges which produce irritation or peeling. As a result, the person skilled in the art would naturally tend toward the lower concentrations of the examples of Blank and Damani, et al., namely on the order of about 2 wt % in the case of the Blank compositions and on the order of 4% or 7% in the case of the Damani, et al., compositions.

Hence, it cannot be said by any stretch of the imagination that Blank and Damani, et al., either considered alone or in combination, would necessarily (inherently) lead one skilled in the art to the presently claimed invention or produce the function or property of the presently claimed invention. In other words, while it is conceded that both Blank and Damani, et al., teach topical formulas containing salicylic acid for the treatment of skin diseases, neither Blank or Damani, et al., do so by producing a superficial chemical skin peel, and practicing the teachings of Blank and/or Damani does not necessarily lead to the production of a superficial chemical skin peel as presently claimed.

Accordingly, in view of the foregoing remarks, it is submitted that the present claims patentably distinguish over the prior art of record. Reconsideration and withdrawal of the rejections and an early Notice of Allowance are respectfully solicited.

In view of the above, it is submitted that all of the claims presently in the application are in condition for allowance, and an early Notice to that effect is respectfully solicited.

Respectfully submitted,

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(Date)

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Enclosure



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Marked-Up Copy of Claim 1

1. (Twice Amended) A method for effecting a superficial chemical skin peel which comprises topically applying to skin to be treated a solution of salicylic acid containing at least 15 wt % up to a saturation concentration of salicylic acid, based on the weight of the solution, in a dermatologically acceptable, volatile, liquid solvent [which allows], and allowing the salicylic acid to be present as a solution on a surface of the skin for a time sufficient to produce a chemical peel of stratum corneum of the skin with viable epidermis remaining substantially intact.

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